



Guidelines for Medical Necessity Determination for Organ Transplant Procedures

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information MassHealth needs to determine medical necessity for the transplant procedures identified in Section I of these Guidelines. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 433.000 and 450.000 and Subchapter 6 of the *Physician Manual* for information about coverage, limitations, service conditions, and other prior-authorization requirements. Providers serving members enrolled in MassHealth-contracted managed care organizations (MCOs) should refer to the MCO's medical policies for covered services.

MassHealth reviews requests for prior authorization on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions. Site-of-service providers must be enrolled in MassHealth pursuant to 130 CMR 433.403 and 450.212, and the institution must be enrolled in MassHealth pursuant to 130 CMR 415.404 and 450.212.

Section I. General Information

Transplants are procedures that transfer living tissue or organs from one area of the body to another area of the same body, or from a donor to a recipient, for the purpose of maintaining functional integrity of tissue or organs in the recipient. Such procedures are used to treat life-threatening complications resulting from end-stage organ diseases and malignant or non-malignant conditions. These Guidelines apply to liver, heart, lung, heart-lung, single or double organs, pancreas, and small bowel transplants.

Section II. Clinical Guidelines

A. Clinical Coverage

MassHealth determines medical necessity in accordance with 130 CMR 450.204 for the use of organ transplants for treatment of end-stage organ failure by considering multiple circumstances. When reviewing requests for prior authorization of organ transplants, MassHealth is guided by current scientific literature and the likelihood of benefit to the member. Transplants may be medically necessary to treat end-stage organ failure caused by a variety of conditions, including, but not limited to:

1. congenital maldevelopment;
2. failure of a vital organ function;
3. trauma or toxic insult;
4. viral or other infection; or
5. primary malignancy.

B. Noncoverage

MassHealth does not ordinarily consider organ transplants to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. The member has a systemic bacterial or fungal infection.
2. The member has a metastatic malignancy.
3. The member has a large tumor (for example, 5 cm or greater).
4. A tumor has extended beyond the confines of the member's transplant organ or is close to a margin of the organ (less than .5 cm).
5. There is significant failure of one or more of the member's other organs or systems. In some circumstances, transplantation may be considered in the face of a second organ failure if a combined transplant is medically necessary.
6. The member is actively abusing alcohol or drugs.
7. The member has irreversible disease that significantly impairs or limits quality or duration of life.
8. The member has progressive neurological disease.
9. The member has psychological or social conditions that make the member unable or unlikely to be able to actively participate in the disciplined medical regimens required by transplantation.

Section III. Submitting Clinical Documentation

Requests for prior authorization of transplants must be accompanied by clinical documentation that supports the need for the type of procedure being requested. Providers must submit a package of information that includes a MassHealth Prior Authorization Request form and **all** of the following:

- A. a letter of medical necessity from the relevant transplant surgeon or specialist (for example, cardiac surgeon for heart, or pulmonologist for lung) describing the type and need for the procedure being requested;
- B. a summary of the member's medical history that includes:
 1. the primary diagnosis name and ICD-CM code specific to the condition requiring the transplant;
 2. the date the member was diagnosed with the medical condition requiring the transplant; and
 3. the initial and recent clinical evaluation(s);
- C. documentation of current medical evaluation that includes all of the following:
 1. **diagnostic studies and laboratory tests** – results of studies and tests deemed relevant to the type of transplant being requested that have been conducted in the last six months;
 2. **medication regimen** – the type and name of prescription and over-the-counter drugs the member has received within the last three to six months;
 3. **risk factors** – a statement that includes current medical or comorbid conditions (for example, neurologic disease, cardiovascular disease, diabetes, or HIV), surgeries or procedures, functional status, or cognitive function that may contraindicate the proposed transplant procedure or postoperative recovery;
 4. **psychiatric history** – a statement from the transplant team's psychiatrist that includes information on the member's mental status, history and screening of alcohol or drug use with a statement attesting to a period of abstinence, the psychiatrist's expectation that the member will adhere to a disciplined medical regimen (including counseling program if needed), and other issues that may affect postoperative recovery;
 5. **psychosocial evaluation** – a statement from the transplant team's coordinator or social worker that includes information on the member's social support system, household living status, work history, and list of caregivers available to assist with care plan requirements; and

6. **care plan** – a summary of the follow-up care plan to manage and monitor postoperative recovery for medical complications, pharmacological therapy, nutritional support, social support, and other pertinent information, including a list of providers (individuals and facilities) responsible for providing and monitoring the care plan;
- D. a list of the transplant team members (for example, transplant specialist and psychiatrist) involved in determining whether the member is eligible for the proposed transplant procedure(s), including the names and contact information for in-state and out-of-state providers; and
- E. for out-of-state requests, the reason that the transplant cannot be performed in state and information identifying which in-state facility will assume postoperative and ongoing medical care of the patient when the patient is determined to be stable by both the in-state transplant specialist and the out-of-state facility.

MassHealth bases its determination of medical necessity for transplant procedures on a combination of clinical data and the presence of indicators that would complicate surgery and affect postoperative recovery. MassHealth evaluates individual medical circumstances in accordance with its medical necessity definition at 130 CMR 450.204.

Select References

MassHealth Provider Manual Series: *Acute Inpatient Hospital Manual*.

MassHealth Provider Manual Series: *Physician Manual*.

Organ Procurement and Transplantation Network (2003). Organ Distribution Policies and Bylaws. Available at: www.optn.org.

United Network for Organ Sharing (UNOS): MELD and PELD information for liver transplant. Available at: www.unos.org.

These Guidelines are based on review of the most current medical literature, standards set by federally designated organ procurement organizations, and federal and state policies applicable to Medicaid programs. The contents of these Guidelines may change or be updated periodically as new clinical evidence emerges.

Policy Effective Date: April 1, 2005

Approved by: , Medical Director